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PharmaCyte Biotech Files Patent Applications to Broaden Protection of Cancer Therapy in U.S. and Worldwide

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, today announced that it has filed a U.S. patent application with the United States Patent and Trademark Office (USPTO) to protect its therapy to treat cancerous tumors, including the therapy that will be used in its upcoming clinical trial in locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC). PharmaCyte has also filed a Patent Cooperation Treaty (PCT) application, which includes protection of its technology in about 150 different countries outside the United States. Both the U.S. and PCT applications claim a priority date from a U.S. provisional patent application PharmaCyte filed in March of last year.

The patent applications specifically include methods of treating many types of solid cancerous tumors, such as those of the pancreas, liver, breast and colon, using the live-cell encapsulation of genetically modified human cells that overexpress a form of the cytochrome P450 enzyme system normally found in the liver. These cells are encapsulated using the Cell-in-a-Box® technology. Together with low doses of oxazaphosphorines, such as ifosfamide, the encapsulated cells comprise PharmaCyte's therapy for cancerous tumors. The patent application also includes using PharmaCyte's platform technology with cyclophosphamide, another chemotherapy drug that must be activated by the cytochrome P450 enzyme system. PharmaCyte believes these technologies will be beneficial to patients who no longer respond to standard chemotherapies, such as gemcitabine and Abraxane®.

These new applications, if granted, will provide protection for PharmaCyte's technology for 20 years – until March 2038. "By filing these patent applications, we are continuing the process of pursuing patent protection for 20 years to protect our therapy for all forms of solid malignant tumors. This is particularly important to the company as we are taking steps to embark upon a clinical trial in LAPC," said PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner.

PharmaCyte's pancreatic cancer therapy was designated an orphan drug and listed in the official registry of medicinal products for rare diseases by the U.S. Food and Drug Administration (FDA) on December 17, 2014. Orphan drug exclusivity would provide marketing exclusivity for PharmaCyte's pancreatic cancer therapy in the U.S. for 7 years after market approval by the FDA. Similarly, PharmaCyte has orphan drug status in the European Union (EU) for its pancreatic cancer therapy, which provides 10 years of

marketing exclusivity in all countries in the EU following approval by the European Medicines Agency (EMA).

In addition, the Biologics Price Competition and Innovation Act (BPCIA), which was enacted as part of the Affordable Care Act in 2010, establishes a period of 12 years of "data exclusivity" for reference products to preserve incentives for future innovation. Under this framework, data exclusivity protects the data in the innovator's regulatory application by prohibiting others, for a period of 12 years, from gaining FDA approval based in part on reliance on or reference to the innovator's data in a biosimilar application. PharmaCyte's 12-year exclusivity will begin as soon as the FDA approves the company's first Cell-in-a-Box®-based therapy.

Mr. Waggoner concluded by stating, "While these patent applications should make our investors feel assured about the protection of our pancreatic cancer therapy, they should understand that if our therapy receives FDA approval, the orphan drug designation in the U.S. and the EU, together with the BPCIA data exclusivity that may be awarded, will give us substantial marketing exclusivity for our pancreatic cancer therapy. These patent applications should be viewed as an opportunity to dramatically broaden PharmaCyte's ability to protect its unique therapy for all malignant solid tumors for the next 20 years."

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage biotechnology company developing cellular therapies for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." This technology will be used as a platform upon which therapies for several types of cancer and diabetes are being developed.

PharmaCyte's therapy for cancer involves encapsulating genetically engineered human cells that convert an inactive chemotherapy drug into its active or "cancer-killing" form. For pancreatic cancer, these encapsulated cells are implanted in the blood supply to the patient's tumor as close as possible to the site of the tumor. Once implanted, a chemotherapy drug that is normally activated in the liver (ifosfamide) is given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide flows through pores in the capsules, the live cells inside act as a "bio-artificial liver" and activate the chemotherapy drug at the site of the cancer. This "targeted chemotherapy" has proven effective and safe to use in past clinical trials and results in no treatment related side effects.

PharmaCyte's therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes involves encapsulating a human cell line that has been genetically engineered to produce, store and release insulin in response to the levels of blood sugar in the human body and/or beta islet cells. The encapsulation will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient, they will function as a "bio-artificial pancreas" for purposes of insulin production.

Safe Harbor

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement because of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements due to the impact of numerous risk factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

More information about PharmaCyte Biotech can be found at www.PharmaCyte.com. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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